> "Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Commissioner shall ... reissue the patent."

Further, in MPEP 1412.01:

> "The reissue claims must be for the same invention as that disclosed as being the invention in the original patent ... This does not mean that the invention claimed in the reissue must have been claimed in the original patent ... The entire disclosure ... is considered in determining what the patentee objectively intended as his invention..."

In 37 CFR 1.175, it is stated:

> "Applicants must file a ... declaration as follows: (3) when it is claimed that such patent is inoperative or invalid by reason of the patentee claiming more or less than he had a right to claim in the patent..."
>
> (emphasis added)

From an overall consideration of these sections of the MPEP and 37 CFR, it is clear that the language "had a right to claim" and "the invention claimed in the reissue doe not have to be that claimed in the original patent" certainly entitles Applicants to utilize the avenue of reissue to adequately protect that which is the invention and the scope of which is readily apparent from a

consideration of the specification in toto.

Applicants' invention is that of providing for the protection of ocular tissue during the rigors of ophthalmic surgery to guard against irreparable damage to such tissue. As is disclosed in the specification at page 1, it is known that ophthalmic surgical procedures currently employ a viscoelastic medium as a method to render protection to ocular tissues during ophthalmic surgery, wherein sodium hyaluronate is injected as the viscoelastic protective gel in common practice. As further disclosed, such method of protection has been found to be less than totally satisfactory, in that not only must great care be exercised when this method of protection is employed, but additionally the use of hyaluronate has resulted in undesirable post-operative conditions, such as pressure elevations, dilation and adhesion development.

Applicants have provided a method whereby post-operative complications which may result from ophthalmic surgery utilizing present day viscoelastic gel media are eliminated by employing in the protective method the particular viscoelastic gel composition disclosed and claimed in the patent and the present application. No

other use is disclosed for this particular, novel composition other than in a method for protecting ocular tissue during ophthalmic surgery, and no other use has been contemplated by Applicants other than as a method, or in a method, for so protecting ocular tissue during surgery. Applicants respectfully submit that the invention disclosed in the specification, that of a method for protecting ocular tissue during surgery wherein a viscoelastic gel is utilized by substituting Applicants' particular gel composition for known compositions entitles Applicants to method claims as well as claims to the novel viscoelastic gel, and that the declaration submitted with the Application is not defective, as has been contended by the Examiner.

Further, Applicants respectfully submit that the claims as now presented are drawn to the same invention as that disclosed in the original patent, for the reasoning hereinbefore set forth.

Reconsideration and withdrawal of these grounds of rejection is therefore respectfully requested.

The method claims stand as rejected under 35 USC 112, it being the position of the Examiner that "acrylamide or methacrylamide or copolymers thereof" encompasses a scope

of subject matter which is broader than warranted or supported.

At column 1, last paragraph, of the patent, it is stated that:

> "The polyacrylamides found to be effective ... having a molecular weight of from about 1 to about 6 million, produced by the polymerization of acrylamide, methacrylamides, or mixtures thereof."

Such language clearly indicates that the term "copolymers thereof" extends only to the products resulting from the polymerization of a mixture of acrylamide and methacrylamide n=monomers and that the inclusion of any other monomer is not intended to be included. Generic method claim 16 and product claim 1 now recite "a copolymer of acrylamide and methacrylamide" which should serve to remove this ground of rejection and which terminology is fully supported by the specification.

Claims 7-15, have been rejected by the Examiner under 35 USC 112 as failing to particularly point out and distinctly claim the subject matter regarded as the invention (a) in the use of the phrase "effective amount" which is considered as failing to make clear either the effect desired or expected or the amount intended, (b) in

"acrylamide or methacrylamide polymers or copolymers, (c) in the failure to set forth the means and modes of administration, (d) in failing to identify the role that the gel is intended to play, and (e) in failing to identify the "surgical method".

Applicants respectfully submit that, with the rewriting of generic method claim as new claim 16 and with the amendments herein to dependent claims 8-15, the aforementioned bases for rejecting these claims under 35 USC 112 are not longer applicable. Generic claim 16 recites the mode of administration as by injection, support for which is to be found in the specification at column 1. The term "effective amount" has been modified to recite "an amount of viscoelastic gel sufficient to prevent mechanical damage and denudation of the ocular tissue". The use of a viscoelastic gel per se in the area of ocular surgery is well-known, as Applicants discuss at column 1 of the patent for which this reissue is sought, and the amounts of gel; volume-wise, to be employed in achieving desired pressure and consistency levels well within the purview of those of ordinary skill in the art.

The "mode of administration" set forth in the

specification is by injection or the gel into the eye. Generic claim 16 so specifies this mode of delivery. Further, generic composition claim 1 specifies that the composition is "injectionable".

Also, the "role played" by the composition in ophthalmic surgery is, as set forth in the specification, and in newly presented method claim 16 is that of preventing mechanical damager and denudation of the ocular tissue.

Finally, the "surgical method" is identified in claim 17 as preferably an anterior segment surgical procedure, and in claim 18 as an anterior surgical procedure selected from such diverse operations as cataract removal, corneal transplant, keratoplasty and bullous rhegmatogenous retinal detachment. Such claim language is fully supported by the specification.

Applicants respectfully submit that, in view of the claims as now presented, the 35 USC 112 rejections applied by the Examiner are no longer applicable, and withdrawal thereof is earnestly solicited.

Claim 15 stands as rejected under 35 USC 112 as containing material for which there is no antecedent basis or support in the specification as filed,

specifically in "about 0.03 percent by weight sodium citrate dihydrate". Claim 15, as originally presented, should have been identical in composition to claim 6 of the patent. However, and erroneously, magnesium chloride hexahydrate was omitted and the "0.03" value erroneously assigned to sodium citrate dihydrate. By the present amendment, claim 15 has been corrected to include both the magnesium chloride hexahydrate and sodium citrate dihydrate, with the correct amounts of each specified. Hence, this ground of rejection is no longer applicable.

The method claims stand as rejected under 35 USC 103 as being unpatentable over Krohn et al, Rankin, Leong et al and Lemp et al.

The reliance upon the Leong et al disclosure is not understood. Leong et al are concerned with conducting comparative transverse strength tests on a heat-polymerized poly(methyl methacrylate) and a chemically-activated polymerization product of methyl methacrylate. No teaching of a use, a gel, or of polymeric polyacrylamides or polymethacrylamides is contained in Leong et al. Hence, this reference has no bearing upon the invention disclosed and claimed in the present application.

Lemp et al disclose studies of a number of surface-active polymers including methyl cellulose, carboxymethyl cellulose, several hydroxyalkyl-celluloses, polyvinylalcohol, and PVP as ocular wetting agents, with studies centering on surface tension, interfacial tension at an oil-water interface, contact angle on the cornea and on poly (methyl methacrylate). No teaching is available from or suggested by this Chemical Abstract art as to the injection of a polyacrylamide gel as useful in ophthalmic surgical procedures to protect the ocular tissue from mechanical damage. Indeed, the abstract is devoid of any reference to ophthalmic surgery, an acrylic or methacrylic based amide polymer or a gel thereof.

Krohn et al disclose an ophthalmic ointment containing a polymer of "well-defined average molecular weight of from about 15,000 to about 500,000 (column 3, lines 39-42), water and a selected medicament, the polymer being present in the ointment in amounts of from 12 to 35 percent by weight, or higher (column 4, lines 1-6). Hence, Krohn et al simply disclose an ophthalmic ointment for effecting delivery of a medicament to the corneal surface of an eye. Neither Applicants method of use nor compositions are disclosed or suggested by the Krohn et

al reference.

Rankin teaches an ophthalmic solution containing a polyacrylamide polymer having a molecular weight of from 75,000 to 10,000,000, water, and, as an optional ingredient, a polyalkylene glycol. Such solutions are disclosed as used to treat "dry eye" by providing a synthetic tear film on the surface of the eye, to deliver selected medicaments to the surface of the eye, to provide a cleansing and cushioning film for hard and soft contact lenses, or to provide a cleansing, lubricating and cushioning agent for the eye after an injury or after therapeutic surgery. As taught by Rankin, the optic surface treatment compositions are solutions, Rankin stating at column 2, lines 43-44:

> "... the polyacrylamides form true solutions ... free of gel particles ..."

Additives which may be optionally included in the compositions of Rankin include polyalkylene glycols, medicaments, phosphate, carbonate or acetate buffers, cellulose derivatives, a biocide, PVP, and nonionic surfactants.

As can be readily seen, Rankin neither discloses nor suggests the viscoelastic gel composition of the present application nor the use of a gel composition for

protecting ocular tissue during ophthalmic surgery, instead teaching a solution of polyacrylamide for application to the surface of the eye only after surgery. Such disclosure does not serve to render obvious Applicants' disclosed and claimed method to those of skill in the art.

Reconsideration and withdrawal of the rejection of the claims as unpatentable over the teachings of the references of record is therefore respectfully requested.

Applicants respectfully submit that the present reissue application meets the requirements for reissue, that the claims as now presented define patentable subject matter, are fully supported by the specification and are in condition for allowance. An early indication of allowability is therefore respectfully requested.

Respectfully submitted,

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